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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,870	07/23/2003	Howard J. Jacob	650053.00002	8005
26710	7590	08/08/2006	EXAMINER	
QUARLES & BRADY LLP 411 E. WISCONSIN AVENUE SUITE 2040 MILWAUKEE, WI 53202-4497				POPA, ILEANA
		ART UNIT		PAPER NUMBER
				1633

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/625,870	JACOB ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ileana Popa	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 18 May 2006.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-15 is/are pending in the application.
  - 4a) Of the above claim(s) 1-10 and 13-15 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 11 and 12 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 23 July 2003 is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

**DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.
2. Claims 1-10 and 13-15 have been withdrawn. Claims 11 and 12 have been amended to recite a rat model obtained from a cross between a FHH and a GK rat. No new matter was introduced by these amendments.

Claims 11 and 12 are under examination.

***Response to Arguments***

***Claim Rejections - 35 USC § 112 – written description***

2. The rejection of claims 11 and 12 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in response to Applicant's amendments and arguments filed on 05/18/2006.

***Claim Rejections - 35 USC § 112 – enablement***

3. The rejection of claims 11 and 12 under 35 U.S.C. 112, first paragraph for failing to comply with the enablement requirement is withdrawn in response to Applicant's amendments to the claims filed on 05/18/2006.

***Claim Rejections - 35 USC § 102***

4. The rejection of claim 11 under 35 U.S.C. 102(b) as being anticipated by Nakamura et al. (Diabetes, 1997, 46: 895-899) is withdrawn in response to Applicant's amendment to the claim filed on 05/18/2006.

***Claim Rejections - 35 USC § 103***

5. The rejection of claim 12 under 35 U.S.C. 103(a) as being unpatentable over Nakamura et al., in view of Sone et al. (Trends in Molecular Medicine, 2001, 7: 3230-322) is withdrawn in response to Applicant's amendment to the claim filed on 05/18/2006.

***New Rejections***

***Claim Rejections - 35 USC § 112 – enablement***

6. Claims 11 and 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel biological materials, specifically a T2DN rat obtained from a cross between a Fawn Hooded rat and a GK rat. Because the biological materials are essential to the claimed invention they must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the

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public. Although the specification discloses a repeatable process to obtain the biological materials, the process is tedious and requires undue experimentation. Moreover, it is not apparent if the biological materials are readily available to the public. If the biological materials are not so obtainable or available, the requirements of 35 USC §112 may be satisfied by a deposit of the biological materials.

\*\*The following is a citation from MPEP

#### **2404 Need or Opportunity to Make a Deposit**

37 CFR 1.802. Need or opportunity to make a deposit.

- (a) Where an invention is, or relies on, a biological material, the disclosure may include reference to a deposit of such biological material.
- (b) Biological material need not be deposited unless access to such material is necessary for the satisfaction of the statutory requirements for patentability under 35 U.S.C. 112. If a deposit is necessary, it shall be acceptable if made in accordance with these regulations. Biological material need not be deposited, *inter alia*, if it is known and readily available to the public or can be made or isolated without undue experimentation. Once deposited in a depository complying with these regulations, a biological material will be considered to be readily available even though some requirement of law or regulation of the United States or of the country in which the depository institution is located permits access to the material only under conditions imposed for safety, public health or similar reasons.

- (c) The reference to a biological material in a specification disclosure or the actual deposit of such material by an applicant or patent owner does not create any presumption that such material is necessary to satisfy 35 U.S.C. 112 or that deposit in accordance with these regulations is or was required.

##### **2404.01 Biological Material That Is Known and Readily Available to the Public**

In an application where the invention required access to specific biological material, an applicant could show that the biological material is accessible because it is known and readily available to the public. The concepts of "known and readily available" are considered to reflect a level of public accessibility to a necessary component of an invention disclosure that is consistent with an ability to make and use the invention. To avoid the need for a deposit on this basis, the biological material must be both known and readily available - neither concept alone is sufficient. A material may be known in the sense that its existence has been published, but is not available to those who wish to obtain that particular known biological material. Likewise, a biological material may be available in the sense that those having possession of it would make it available upon

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request, but no one has been informed of its existence.

The Board of Patent Appeals and Interferences has held that a description of the precise geographic location of marine tunicates, as a biological material, used in a claimed invention was adequate to satisfy the enablement requirement of 35 U.S.C. 112. Ex Parte Rinehart, 10 USPQ2d 1719 (Bd. Pat. App. & Int. 1985). The term "readily" used in the phrase "known and readily available" is considered appropriate to define that degree of availability which would be reasonable under the circumstances. If the biological material and its natural location can be adequately described so that one skilled in the art could obtain it using ordinary skill in the art, the disclosure would appear to be sufficient to meet the enablement requirement of 35 U.S.C. 112 without a deposit so long as its degree of availability is reasonable under the circumstances.

By showing that a biological material is known and readily available or by making a deposit in accordance with these rules, applicant does not guarantee that such biological material will be available forever. Public access during the term of the patent may affect the enforceability of the patent. Although there is a public interest in the availability of a deposited biological material during and after the period of enforceability of the patent, there should not be any undue concern about continued access to the public. See 37 CFR 1.806 (the term of deposit is "at least thirty (30) years and at least five (5) years after the most recent request" for a sample; the agreement sufficiently ensures that the deposit will be "available beyond the enforceable life of the patent"). Unless there is a reasonable basis to believe that the biological material will cease to be available during the enforceable life of the patent, current availability would satisfy the requirement. The incentives provided by the patent system should not be constrained by the mere possibility that a disclosure that was once enabling would become non-enabling over a period of time through no fault of the patentee. In re Metcalfe, 410 F.2d 1378, 161 USPQ 789 (CCPA 1969).

If an applicant has adequately established that a biological material is known and readily available, the Office will accept that showing. In those instances, however, the applicant takes the risk that the material may cease to be known and readily available. Such a defect cannot be cured by reissue after the grant of a patent.

On the other hand, Ex parte Humphreys, 24 USPQ2d 1255 (Bd. Pat. App. & Int. 1992), held that the only manner in which applicants could satisfy their burden of assuring public access to the needed biological material, and, thereby, compliance with the enablement requirement of 35 U.S.C. 112, was by making an appropriate deposit. The fact that applicants and other members of the public were able to obtain the material in question from a given depository prior to and after the filing date of the application in issue did not establish that upon issuance of a patent on the application that such material would continue to be accessible to the public. The applicants did not make of record any of the facts and circumstances surrounding their access to the material in issue from the depository, nor was there any evidence as to the depository's policy regarding the material if a patent would have been granted. Further, there was no assurance that the depository would have allowed unlimited access to the material if the application had matured into a patent.

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There are many factors that may be used as indicia that a biological material is known and readily available to the public. Relevant factors include commercial availability, references to the biological material in printed publications, declarations of accessibility by those working in the field, evidence of predictable isolation techniques, or an existing deposit made in accordance with these rules. Each factor alone may or may not be sufficient to demonstrate that the biological material is known and readily available. Those applicants that rely on evidence of accessibility other than a deposit take the risk that the patent may no longer be enforceable if the biological material necessary to satisfy the requirements of 35 U.S.C. 112 ceases to be accessible.

The Office will accept commercial availability as evidence that a biological material is known and readily available only when the evidence is clear and convincing that the public has access to the material. See the final rule entitled "Deposit of Biological Materials for Patent Purposes," 54 FR 34864, 34875 (August 22, 1989). A product could be commercially available but only at a price that effectively eliminates accessibility to those desiring to obtain a sample. The relationship between the applicant relying on a biological material and the commercial supplier is one factor that would be considered in determining whether the biological material was known and readily available. However, the mere fact that the biological material is commercially available only through the patent holder or the patent holder's agents or assigns shall not, by itself, justify a finding that the necessary material is not readily available, absent reason to believe that access to the biological material would later be improperly restricted.

The mere reference to a deposit or the biological material itself in any document or publication does not necessarily mean that the deposited biological material is readily available. Even a deposit made under the Budapest Treaty and referenced in a United States or foreign patent document would not necessarily meet the test for known and readily available unless the deposit was made under conditions that are consistent with those specified in these rules, including the provision that requires, with one possible exception (37 CFR 1.808(b)), that all restrictions on the accessibility be irrevocably removed by the applicant upon the granting of the patent. *Ex parte Hildebrand*, 15 USPQ2d 1662 (Bd. Pat. App. & Int. 1990).

It is noted that Applicant has not deposited the biological materials. If the deposit is made under the Budapest Treaty, then an affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific biological materials have been deposited under the Budapest Treaty and that the biological materials will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If the deposit has not been made under the Budapest Treaty,

then in order to certify that the deposit meets the criteria set forth in 37 CFR §§1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
- (d) a test of the viability o the biological material at the time of deposit will be made (see 37 CR §1.807); and
- (e) the deposit will be replaced if it should ever become inviable.

Applicant's attention is directed to MPEP §2400 in general, and specifically to §2144.05, as well as to 37 CFR §1.809(d), wherein it is set forth that "the specification shall contain the accession number for the deposit, the date of the deposit, the name and address of the depository, and a description of the deposited material sufficient to specifically identify it and to permit examination." The specification should be amended to include this information, however, Applicant is cautioned to avoid the entry of new matter into the specification by adding any other information. Finally, Applicant is advised that the address for the ATCC has recently changed, and that the new address should appear in the specification. The new address is:

American Type Culture Collection  
10801 University Boulevard  
Manassas, VA 20110-2209

***Conclusion***

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ileana Popa whose telephone number is 571-272-5546. The examiner can normally be reached on 9:00 am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ileana Popa

  
Janet S. Gysford  
Primary Examiner  
AV 1633